REMARKS

Claim Status

Claims 1 – 11 and 15 – 52 are pending in the present application. No additional claims fee is believed to be due.

Claims 12 – 14 were previously canceled without prejudice.

Independent Claims 1 and 40 are amended herein. Support for the amendments is found at page 13, lines 8-9 of the specification.

It is believed these changes do not involve any introduction of new matter. Consequently, entry of these changes is believed to be in order and is respectfully requested.

Rejection Under 35 U.S.C. §103(a)

In Paragraph 4 of the Office Action dated 01/22/09, Claims 1-11, 15-19, 21-25, 36-39 and 40-52 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Everhart, et al. (USPN 5,468,236).

In Paragraph 5 of the Office Action dated 01/22/09, Claims 28-35 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Everhart, et al. (USPN 5,468,236) in view of Al-Sabah (USPN 5,868,723).

Applicants respectfully traverse the rejections.

Under MPEP §2142, the Office bears the burden of factually supporting an asserted *prima facie* conclusion of obviousness. In determining the differences between the cited art and the claims, the question is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. *See, e.g., Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1537; 218 U.S.P.Q. 871 (Fed. Cir. 1983). If the Office does not demonstrate *prima facie* unpatentability, then without more, the Applicant is entitled to the grant of the patent. *See In re Oetiker*, 977 F.2d 1443, 1445; 24 U.S.P.Q.2d 1443 (Fed. Cir. 1992).

To establish a *prima facie* case of obviousness under 35 U.S.C. §103, the Office must show that all of the claim elements are taught or suggested in the prior art. *See, e.g., CFMT, Inc. v. Yieldup Int'l Corp.*, 349 F.3d 1333, 1342; 68 U.S.P.Q.2d 1940 (Fed. Cir. 2003).

Independent Claims 1 and 40, as amended, both recite an article comprising, *inter alia*, a "biosensor including at least one bio-recognition element comprising a biologically derived material and adapted to interact selectively with one or more pathogenic microorganisms." By dependency, all remaining pending claims include these elements.

Without conceding the teaching or suggestion of any other elements of the independent claims in the references cited, and without waiving any other arguments they may have, Applicants respectfully submit that neither Everhart et al. nor Al-Sabah, alone or in combination, teach or suggest an article comprising the biosensor element as recited.

Applicants' specification describes the biosensor in part as follows:

> . . . As used herein, the term "biosensor" is defined as a component comprising one or more biologically reactive means being adapted to detect one or more target pathogenic microorganisms or related biomolecules (e.g., an enzyme sensor, organella sensor, tissue sensor, microorganism sensor, immunosensor or electrochemical sensor), additionally having the capability to provide a signal of said detection to the wearer, caretaker, or an actuator. The term "biologically reactive" is defined as having the capability to selectively interact with, and preferably bind, target pathogenic microorganisms and/or related biomolecules as described herein. Generally, biosensors function by providing a means of specifically binding, and therefore detecting, a target biologically active analyte. In this way, the biosensor is highly selective, even when presented with a mixture of many chemical and biological entities, such as feces. Chemical sensors, on the other hand, which rely on chemically reactive means, generally do not have either the high selectivity or the amplification properties of biosensors and, therefore, are not well suited to detect biologically reactive analytes, especially when they are present in low concentrations and/or in a complex media such as bodily waste. Often the target biological analyte is a minor component of a complex mixture comprising a multiplicity of biological and other components. Thus, in many biosensor applications, detection of target analytes to the parts-per-billion, parts-per-trillion, or even lower levels is necessary. Accordingly, discrimination ratios of about 10^7-10^8 or greater may be

> required for the biosensor to recognize the target biological analyte in a complex mixture.
>
> The biosensor of the present invention comprises a bio-recognition element, or molecular recognition element, that provides the highly specific binding or detection selectivity for a particular analyte. The bio-recognition element, or system, may be a biologically derived material such as an enzyme or sequence of enzymes; an antibody; a membrane receptor protein; DNA; an organelle, a natural or synthetic cell membrane; an intact or partial viable or nonviable bacterial, plant or animal cell; or a piece of plant or mammalian tissues, and generally functions to interact specifically with a target biological analyte. The bio-recognition element is responsible for the selective recognition of the analyte and the physico-chemical signal that provides the basis for the output signal.

(Specification, p. 12, lines 20-33; p. 13, lines 1-14.)

Everhart et al. does not teach or suggest a biosensor including at least one bio-recognition element. Everhart et al. discloses a "chemically reactive means," which is *unspecified* except for two examples. In the first example, a "chemically reactive means" is described as adapted to give a visual indication of glucose concentration in urine. (Everhart et al., col. 7, lines 44-46.) In the second example, another "chemically reactive means" is described as adapted to detect nitrite in urine. (Everhart et al., col. 10, lines 43-59.)

In the Office Action dated 1/22/09, the Office equates Everhart et al.'s "chemically reactive means" which may be selected such that it will detect a "substance", *e.g.*, "specific enzymes" (Everhart et al. Col. 3, lines 48-60), with an example of a biosensor identified in Applicants' specification – an "enzyme sensor" (Specification, page 12, lines 20-24). (Office Action dated 1/22/09, ¶ 1.) Applicants respectfully submit that this reading of Everhart et al. and interpretation of the term "enzyme sensor" are not supported. Applicants further submit that the broad interpretation of Applicants' claim term "biosensor" such that it reads onto Everhart's "chemically reactive means" is inconsistent with the description of "biosensor" Applicants' specification – and therefore, incorrect.

Everhart et al. does not identify or describe an "enzyme sensor" by that term. Assuming, *arguendo*, that a chemically reactive means that can detect an enzyme (such as vaguely identified in Everhart el al.) might at first pass be labeled an "enzyme sensor," consideration must be given what the term "enzyme sensor" would mean to a person of ordinary skill in the art. Applicants respectfully submit that the term "enzyme sensor," in the context of Applicants' specification, would be understood by a person of ordinary skill in the art to mean a biosensor that *comprises* an enzyme – not merely any sensor that can detect an enzyme. *See, e.g.*, U.S. Patent No. 5,830,341, issued to Gilmartin, at Col. 4, line 65 to Col. 5, line 3, describing an electrode comprising an enzyme layer. (USPN 5,830,341 is cited and incorporated by reference in Applicants' specification at page 16, line 5.)

Further, Applicants' Specification expressly distinguishes a "biosensor" from mere "chemically reactive means" such as disclosed by Everhart et al.:

> Generally, biosensors function by providing a means of specifically binding, and therefore detecting, a target biologically active analyte. In this way, the biosensor is highly selective, even when presented with a mixture of many chemical and biological entities, such as feces. Chemical sensors, on the other hand, which rely on chemically reactive means, generally do not have either the high selectivity or the amplification properties of biosensors and, therefore, are not well suited to detect biologically reactive analytes, especially when they are present in low concentrations and/or in a complex media such as bodily waste.

(Specification at page 12, lines 27-33.)

Applicants respectfully submit that it is not correct to read a claim term in a manner that is inconsistent with Applicants' use of the term in the specification, in order to support a conclusion of obviousness. Although it is correct that "[d]uring the patent examination process, claims receive their broadest reasonable meaning," "this does not relieve the PTO of its essential task of examining the entire patent disclosure to discern the meaning of claim words and phrases." *Rowe v. Dror*, 112 F.3d 473, 480, 42 U.S.P.Q.2d 1550, 1555 (Fed. Cir. 1997); *see also In re Morris et al.*, 127 F.3d 1048,

1054, 44 U.S.P.Q.2d 1023 (Fed. Cir. 1997) ("it would be unreasonable for the PTO to ignore any interpretive guidance afforded by the applicant's written description"). *See also* MPEP §§ 2111, 2111.01.

Finally, neither Everhart et al. nor Al-Sabah et al. teaches or suggests a bio-recognition element comprising a biologically derived material, as recited by the independent claims.

For the foregoing reasons, it is respectfully submitted that neither Everhart et al. nor Al-Sabah, alone or in combination, supports a *prima facie* conclusion of obviousness of Applicants' claims as amended. Applicants, therefore, respectfully request that the rejections of claims 1-11 and 15-52 under 35 U.S.C. §103(a) be reconsidered and withdrawn.

Conclusion

This response represents an earnest effort to place the present application in proper form for allowance. In view of the foregoing, reconsideration of this application, and allowance of the pending claims are respectfully requested.

Respectfully submitted,

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